UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

7/28/2017

SUBJECT: Acute Toxicity Review for Myacide GA 45, EPA Reg. No.: 33753-27

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Registrant: BASF Corporation		
Decision No.: 508663	Submission No.: 991341	E-Sub No.: n/a
DP No.: 435964	Action Code: 676	
MRID No(s).: 00117061, 00164370, 44691606, 49793003, 00060275, 49921104, 49921105, 00117064, 00117065, 00117066, 00117067, 00117068, 00117060, 43330201		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
043901	111-30-8	Glutaraldehyde	45.0
		Other Ingredients	55.0
		Total	100.0

I. BACKGROUND

The Registrant, BASF Corporation, has submitted an acute 6-pack toxicity data to support the PDCI (043901-30503) for Reregistration case 2315 for their product: *Myacide GA 45*, EPA Reg. No. 33753-27.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-35 – Data Matrix (8/12/2016)	☒	☐
Cover letter (8/16/2016)	☒	☐
Transmittal document	☒	☐
Basic CSF, (8/12/2016)	☒	☐
Proposed label, (6/1/2016)	☒	☐
	☐	☐
Acute Oral Toxicity Study (OSCPP 870.1100)	☒	☐
Acute Dermal Toxicity Study (OSCPP 870.1200)	☒	☐
Acute Inhalation Toxicity Study (OSCPP 870.1300)	☒	☐
Primary Eye Irritation Study (OSCPP 870.2400)	☒	☐
Primary Skin Irritation Study (OSCPP 870.2500)	☒	☐
Dermal Sensitization Study (OSCPP 870.2600)	☒	☐

III. FINDINGS/RECOMMENDATIONS

3.1. Acute Oral toxicity (OSCPP 870.1100)

3.1.1. MRID 00117061 presents the Acute Oral toxicity study conducted by none of the methods recommended in OSCPP 870.1100 Guideline as well as without GLP and Quality assurance statements. The MRID is not acceptable.

3.1.2. MRID 00164370 provides the Acute Oral toxicity study conducted by none of the methods recommended in OSCPP 870.1100 Guideline. The MRID is not acceptable.

3.2. Acute Dermal toxicity (OSCPP 870.1200)

3.2.1. The bridging request in MRID 49793003 for the Acute Dermal toxicity study is based on the data provided in MRID 44691606 that is cited in the Reregistration Eligibility Decision document (RED). Since the cited study used the test substance containing 50.2% of the active ingredient (versus 45.0% in the subject product), the bridging is granted with the assignation of Category III to the Acute Dermal toxicity endpoint.

3.3. Acute Inhalation toxicity (OSCPP 870.1300)

3.3.1. The bridging request in MRID 49793003 for the Acute Inhalation toxicity study is based on the data provided in MRID 0060275 that is cited in the RED. Since the conditions and output data of the cited study do not meet the contemporary requirements of Guideline OSCPP 870.1300, the bridging is not granted.

3.3.2. Data provided in MRID 49921104 do not contain mandatory information about the MMAD and GSD. The study is not acceptable.

3.3.3. Data provided in MRID 49921105 indicate that MMAD and GSD were not calculated since the test substance was available as a very fine aerosol <2.8 µm or as a vapor. As per OSCPP 870.1300, to assess the inhalation toxicity, the MMAD particle size range should be between 1- 4 µm. The study is not acceptable.

3.4. Primary Eye irritation (OSCPP 870.2400)

3.4.1. The bridging request in MRID 49793003 for the Primary Eye irritation study is based on the data provided in MRIDs 00117064, 00117065, 0117066, 0117067 and 00117068. Although the conditions and output data of the cited studies do not meet the contemporary requirements of Guideline OSCPP 870.2400, the bridging is granted (for reregistration purposes only) since the above five studies were tested on a very dilute product and classify the test material as Toxicity Category I.

3.5. Primary Skin irritation (OSCPP 870.2500)

3.5.1. Data provided in MRID 00117060 indicate that the test substance used in the study has 25% of the active ingredient *versus* 45% in the subject product. The study is not acceptable. Nevertheless, the Category I evaluated in the study can be assigned to this endpoint as the highest level of toxicity classification (for reregistration purposes only).

3.5.2. MRID 00117061 is erroneously listed in the Data Matrix as pertained to the Primary Skin irritation endpoint.

3.6. Skin sensitization (OSCPP 870.2600)

3.6.1. The LLNA test procedure provided in MRID 43330201 does not meet the requirements of guideline OSCPP 870.2600. In particularly, there were 4 mice in each dose group versus a minimum of 5 animals as per the Guideline for this endpoint. The study is not acceptable. Nevertheless, the skin sensitization potential evaluated in the study can be assigned to this endpoint as a more conservative assessment (for reregistration purposes only).

3.7. The acute toxicity profile of *Myacide GA 45*, EPA Reg. No. 33753-27 is currently:

GRN	Study	MRID	Toxicity Category	Status
870.1100	Acute Oral Toxicity	00111706, 00164370	Undetermined	Unacceptable/Data gap
870.1200	Acute Dermal Toxicity	44691606, 49793003	III	Bridged
870.1300	Acute Inhalation Toxicity	00060275, 49793003, 49921104, 49921105	Undetermined	Unacceptable/Data gap
870.2400	Primary Eye Irritation	00117064, 00117065, 00117066, 00117067, 00117068, 49793003	I	Bridged*
870.2500	Primary Skin Irritation	00117060	I	Assigned*
870.2600	Dermal Sensitization	43330201	Sensitizer	Assigned*

* For reregistration purposes only

IV. CONCLUSION

The acute toxicity requirements have not been satisfied for the subject product EPA Reg. No. 33753-27 primarily because the conditions and results of Acute Oral and Acute Inhalation toxicity studies do not meet the contemporary requirements of the corresponding Guidelines 870.1100 and 870.1300. There are still data gaps for acute oral and acute inhalation toxicity endpoints.

V. PRODUCT LABELING

1. **SIGNAL WORD:** DANGER
2. **HAZARDS TO HUMANS AND DOMESIC ANIMALS:** Cannot be prescribed for EPA Reg. No. 33753-27 due to lack of acceptable acute toxicity data.